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EXAMINER	
GARCIA, M	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/456,429

Applicant(s)

Ji et al

Examiner

Maurie E. Garcia, Ph. D.

Group Art Unit

1627



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ONE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-51 \_\_\_\_\_ is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-51 \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Supervisory Patent Examiner, at (703) 308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-15, drawn to multibinding compounds and pharmaceutical compositions comprising the compounds, classified in various classes depending on the compound, for example, any of class 540-570, subclasses various.
  - II. Claims 16-24, drawn to methods of modulating activity/treatment, classified in various classes depending on the compound and the disease treated, for example, any of classes 514 or 424, subclasses various.
  - III. Claims 25 and 27-39, drawn to a method for identifying multimeric ligand compounds using a library of linkers, classified in class 435, subclass 7.1 or class 436, subclass 501.
  - IV. Claims 26-39, drawn to a method for identifying multimeric ligand compounds using a library of ligands, classified in class 435, subclass 7.1 or class 436, subclass 501.
  - V. Claims 40 and 42-48, drawn to a library of multimeric ligand compounds prepared using a library of linkers, classified in various classes depending on the library compounds, for example, any of class 540-570, subclasses various.
  - VI. Claims 41-48, drawn to a library of multimeric ligand compounds prepared using a library of ligands, classified in various classes

depending on the library compounds, for example, any of class 540-570, subclasses various.

- VII. Claims 49-51, drawn to an iterative method for identifying multimeric ligand compounds, classified in class 435, subclass 7.1 or class 436, subclass 501.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the diseases of the instant claims could be treated with a variety of different compounds and the multibinding compounds could be used as diagnostic agents.

4. Groups I and III, IV & VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the multibinding compounds of Group I could be made by a different process than identification from a library. For example, the compounds could be made based on a computer modeling study.

5. Groups III, IV & VII and V & VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the libraries of Groups V & VI could be used to identify compounds that have multibinding properties for different targets. The methods of Groups III, IV and VII all require that the compounds possess multivalent properties for calcium channels.

6. Groups I, V & VI represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the library of Groups V and VI are compositions comprising at least two members, while Group I represents distinct molecules. Libraries and compounds also have different uses and require different methods of making. The two libraries of Groups V and VI are different because they comprise different compounds and are made from different starting materials (libraries of linkers versus libraries of ligands).

7. Groups II, III, IV & VII are different methods. The methods are different because they use different steps, require different reagents and will produce different products and/or results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the

method of treatment (Group II) is completely different from the methods of identifying multimeric ligand compounds (Groups III, IV & VII), requiring different reagents (single compounds versus libraries) and having completely different end results. The methods of identifying multimeric ligand compounds (Groups III, IV & VII) are different because they each require different steps and require different reagents. Groups III and IV require different libraries or "collections" (linkers versus ligands) and do not have iterative steps. These methods therefore do not require more than one "collection". The method of Group IV requires iterative steps and at least two "collections".

8. Groups V & VI are not related to Group II. The inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the libraries of Groups V & VI are not related to the method of treatment using a single compound (Group II).

9. Groups III & VI and IV & V are not related. The inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the library of Group VI is not used in the method of Group III and the library of Group V is not used in the method of Group IV (see paragraph 6 above).

10. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Please note that even though some of these groups are classified in the same class/subclass, this has no effect on the

non-patent literature search. Different methods and products would require completely different searches in these databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

11. This application contains claims directed to patentably distinct species of the claimed invention for **Groups I-VI**. An election of species is required as set forth below.

12. If applicant elects the invention of **Group I**, applicant is required to elect from the following patentably distinct species.

Species of multibinding compound

Species 1: Homomeric

Species 2: Heteromeric

**NOTE:** If Species 1 is selected then **one** ligand should be further selected from the species below. If Species 2 is selected then **two** ligands should be chosen.

Species of ligand

Applicant is required to elect ligand(s) as set forth above from those set forth in claims 2 and/or 3.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

13. If applicant elects the invention of **Group II**, applicant is required to elect from the following patentably distinct species.

Species of multibinding compound

Species 1: Homomeric

Species 2: Heteromeric

**NOTE:** If Species 1 is selected then **one** ligand should be further selected from the species below. If Species 2 is selected then **two** ligands should be chosen.

Species of ligand

Applicant is required to elect ligand(s) as set forth above from those set forth in claims 17 and/or 18.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

14. If applicant elects the invention of **Group III**, applicant is required to elect from the following patentably distinct species.

Species of library compounds

Species 1: Homomeric	Claims 25, 27, 28, 31-38
Species 2: Heteromeric	Claims 25, 27-37, 39

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

15. If applicant elects the invention of **Group IV**, applicant is required to elect from the following patentably distinct species.

Species of library compounds

Species 1: Homomeric	Claims 26-28, 31-38
Species 2: Heteromeric	Claims 26-37, 39

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

16. If applicant elects the invention of **Group V**, applicant is required to elect from the following patentably distinct species.



Species of library compounds

Species 1: Homomeric

Claims 40, 42-47

Species 2: Heteromeric

Claims 40, 42-46, 48

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

17. If applicant elects the invention of **Group VI**, applicant is required to elect from the following patentably distinct species.

Species of library compounds

Species 1: Homomeric

Claims 41-47

Species 2: Heteromeric

Claims 41-46, 48

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

19. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.


20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

21. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

22. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

24. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).
25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.
26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
**DR. JYOTHSNA VENKAT PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

Maurie E. Garcia, Ph.D.  
January 23, 2001



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